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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/702,037	10/27/2000	Peter Bennett Duff Whyte	U013032-6	8344

7590 11/16/2005
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EXAMINER

WARE, DEBORAH K

ART UNIT PAPER NUMBER

1651

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/702,037

Applicant(s)

WHYTE, PETER BENNETT DUFF

Examiner

Deborah K. Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16/27/05 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f):
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 28-74 are presented for examination on the merits.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on August 19, 2005 has been entered. Further, this case is a continuation of 00/000,317, filed April 30, 1998.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Australia on April 30, 1998. It is noted, however, that applicant has not filed a certified copy of the patent application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 28-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over AU-A-631136/94, WO/97/16977, Clark et al, and newly cited Ballard et al (US 6,319,522), all cited of record on either PTO-892 or PTO-1449 Forms.

Claims are drawn to methods of administering reconstituted dry colostrum of which is prepared by ultrafiltration, spray drying, and reconstituting the dry colostrum. Each of the methods employ administering reconstituted dry colostrum for changing body composition and treating a disorder of the gut.

AU-A-63136/94 teaches a colostrum product prepared by a method comprising subjecting colostrum to ultra-filtration to obtain an ultra-filtered colostrum retentate, and recovering the retentate, wherein said product is further subjected to a spray drying process. Note page 1 and claim 1 of the this cited patent. Also the colostrum is subjected to bacterial reduction using centrifugation. Note page 1, claim 2. The colostrum is also subjected to heat, note page 4, line 31. Temperatures used and disclosed for preparing the colostrum are less than 64 °C and 72 °C, see page 6, line 15.

WO 97/16977 (WO) teach administering effective amounts of compositions containing colostrum, see abstract and page 21, last two lines. Administering is carried out over a period of two weeks, see results of sample times, pages 10-12, Tables 3-6.

Clarke et al teach colostrum contains IGF-1, at column 42, 3rd paragraph, line 7. lines 25-40 of second column. Further, improved body composition and condition is achieved by the presence of IGF-I levels, administered via colostrum note page 44, lines 1-20. Also reduction of muscle damage during exercise by enhancing healing is

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disclosed, see page 44-45, all lines and page 46, lines 22-35. Further, it is also disclosed that colostrum is a food and promotes healing of the body composition by ridding the body of toxins and reducing fatigue, note page 51, lines 30-50 and page 55, lines 8-30. Also improved exercise performance is noted. Further a disorder of the gut is resolved with colostrum, see pages 34-35, all lines.

Ballard et al teach reconstituting dry samples in a buffered saline, note column 26, lines 65-67. Colostrum is disclosed at column 27, line 55.

The claims differ from AU-A-63136/94 (AU) in that changing body composition and treating disorder of the gut, growth factor IGF-1 and administering over a period of weeks as well as improvement of body composition via administering reconstituted colostrum is not disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare colostrum as disclosed by A-63136/94 and administer as a reconstituted dry colostrum for improving body composition and treatment of the disorder of the gut as disclosed by WO 97/16977, Ballard et al, and Clarke et al, respectively. Clearly the process steps of preparing colostrum are well recognized by the cited prior art. To administer colostrum for changing body composition and treating gut disorders is also well recognized and would have been expected to provide successful results. Gut disorder can be E. coli infections, note column 34, of Clarke et al, second paragraph, line 8. The motivation is clearly evidenced by the teaching of Clarke et al to administer colostrum preparations for the intended purpose of the methods as claimed. Each of the claimed limitations are either

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disclosed or suggested by the cited prior art. An improvement in body composition would clearly suggest to one of skill in the art a reduction of fat mass. To administer over a period of 4 week is clearly within the skill of an ordinary artisan especially since the art recognizes successful results for administering over a period of even two weeks. To double the time period for adminisitering colostrum is clearly an obvious modification. Thus, the claims are rendered prima facie obvious over the cited prior art.

Response to Arguments

Applicant's arguments filed August 19, 2005, have been fully considered but they are not persuasive. The argument that the art combination of record, not including Ballard et al, of which is newly applied herein to meet a newly added limitation to the claims, is not remedied with the application of Clarke et al because the deficiencies of AU and WO have not been overcome by Clark et al, is noted. However, applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

With respect to Clarke et al the issue in the applied prior art is that colostrum would have been expected to provide successful results for treating the gut and/or body composition because it has been used before for these intended purposes. Thus, there is no reason one of skill in the art would not expect successful results when the colostrum is subjected to ultrafiltration, spray drying and reconstitution as it is in the instantly claimed subject matter. It is therefore, the examiner's position that all three of

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the criteria for establishing a prima facie case of obviousness have been met and claims are rendered obvious over the newly cited prior art rejection herein.

All claims fail to be patentably distinguishable over the state of the art discussed above and previously cited on the PTO-892 and/or PTO-1449 Forms of record.

Therefore, the claims are properly rejected.

The remaining references listed on the PTO-892 and/or PTO-1449 Forms of record, are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Deborah K. Ware
November 12, 2005



DAVID M. NAFF
PRIMARY EXAMINER
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